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| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | MAILING ADDRESS |
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| 09/993,502 | 11/27/2001 | Alan McClelland | 2048-127 | [REDACTED] |

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SUITE 800
WASHINGTON, DC 20005

EXAMINER

PRIEBEL, SCOTT DAVID

[REDACTED]

EXAMINER APPROVED

DATE MAILED: 06/08/2008

/27

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | | | | | |
|---|---|--|--|--|--|---|---|--|
| Office Action Summary | Application No. 09/993,502 | Applicant(s) McClelland et al. | | | | | | |
| | Examiner Scott D. Priebe, Ph.D. | Art Unit 1632 | | | | | | |
| -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -- | | | | | | | | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | | |
| Status <p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Mar 24, 2003</u>.</p> <p>2a) <input checked="" type="checkbox"/> This action is FINAL. 2b) <input type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p> | | | | | | | | |
| Disposition of Claims <p>4) <input checked="" type="checkbox"/> Claim(s) <u>1-18 and 27</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) _____ is/are withdrawn from consideration.</p> <p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6) <input checked="" type="checkbox"/> Claim(s) <u>1-18 and 27</u> is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p> | | | | | | | | |
| Application Papers <p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p> | | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 <p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p> | | | | | | | | |
| <p>*See the attached detailed Office action for a list of the certified copies not received.</p> <p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> | | | | | | | | |
| <p>15) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p> | | | | | | | | |
| Attachment(s) <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">1) <input type="checkbox"/> Notice of References Cited (PTO-892)</td> <td style="width: 33%;">4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</td> </tr> <tr> <td>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</td> <td>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</td> </tr> <tr> <td>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>9</u></td> <td>6) <input type="checkbox"/> Other: _____</td> </tr> </table> | | | 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ | 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) | 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>9</u> | 6) <input type="checkbox"/> Other: _____ |
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DETAILED ACTION

Election/Restriction

Claims 19-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 12, filed 3/24/03. The cancellation of claims 19-26 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-5, 16, 17 and 27 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Krasnykh et al. (J. Virol. 70(10): 6839-6846, Oct. 1996).

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Krasnykh et al. disclose an adenoviral vector wherein the fiber protein of the otherwise Ad5 vector is a chimera of the Ad5 tail and shaft domains and the Ad3 head or knob domain and a method of using such vector to transduce cells with a DNA segment, the cells comprising a receptor for the Ad3 fiber protein (page 6839, Abstract; page 6839, col. 2, ‘Construction of recombinant plasmids’ through page 6841, full para. 1; page 6842, col. 2 to page 6843, col. 2).

Claims 1-8, 10, 16-18 and 27 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Wickham et al., US 5,770,442.

Wickham et al. disclose adenoviral vectors comprising a gene of interest and having a chimeric fiber protein comprising at least a head region derived from an adenovirus of a serotype other than that used for the vector. One such adenoviral vector disclosed is an Ad5 vector wherein at least the head (or knob) domain is derived from Ad3. The reference discloses pharmaceutical compositions comprising such vectors and methods of using the vectors to transduce cells either *in vitro* or *in vivo*. The reference also discloses that Ad5 vectors comprising the Ad3 head domain have a much broader host cell range than Ad5 vectors with their native fiber protein, being able to infect essentially any higher eukaryotic cell. The reference teaches that the adenoviral vectors can be used to transduce cancer cells, e.g. lung, and in preventing restenosis. (See col. 5, lines 39-50; col. 6, lines 4-8, 52-67; col. 10, lines 4-17, 28-35; col. 11, lines 27-36; col. 12, line 35 to col. 13, line 37; col. 14, line 65 to col. 16, line 34; col. 23-24, claims 1, 11, 13-15.)

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6 and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wickham et al., US 5,770,442.

Wickham et al. disclose adenoviral vectors comprising a gene of interest and having a chimeric fiber protein comprising at least a head region derived from an adenovirus of a serotype other than that used for the vector. One such adenoviral vector disclosed is an Ad5 vector wherein at least the head (or knob) domain is derived from Ad3. The reference discloses pharmaceutical compositions comprising such vectors and methods of using the vectors to transduce cells either *in vitro* or *in vivo*. The reference also discloses that Ad5 vectors comprising

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the Ad3 head domain have a much broader host cell range than Ad5 vectors with their native fiber protein, being able to infect essentially any higher eukaryotic cell. The reference teaches that the adenoviral vectors can be used to transduce cancer cells, e.g. lung, in treating hemophilia, which could involve hematopoietic cells and in preventing restenosis, which would involve transducing smooth muscle cells, or to study the effects of expression of a transgene on a given cell-type *in vitro* and *in vivo*. (See col. 5, lines 39-50; col. 6, lines 4-8, 52-67; col. 10, lines 4-17, 28-35; col. 11, lines 27-36; col. 12, line 35 to col. 13, line 37; col. 14, line 65 to col. 16, line 34; col. 23-24, claims 1, 11, 13-15.)

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to use the method of Wickham et al. of transduction with modified adenovirus vectors having chimeric fiber proteins, e.g. Ad5 vector with Ad3 head domain on the fiber protein, to transfer a DNA sequence into virtually any cell type with a reasonable expectation of success since the Ad3 head domain allows infection of essentially all higher eukaryotic cell types, and for the reasons explicitly stated in the reference as part of gene therapy or to study the effects of expression of a transgene on a given cell-type *in vitro* and *in vivo*.

Conclusion

This is a continuation of applicant's earlier Application No. 08/852,924. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the

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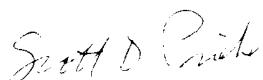
earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Scott D. Priebe, Ph.D.
Primary Examiner